

**STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY**

IN RE:)	
)	
DIERBERGS MARKETS, INC.)	
d/b/a DIERBERGS FENTON CROSSING)	
PHARMACY)	Complaint No. 2015-007038
Permit No: 2000158538)	
450 Old Smizer Mill Rd.)	
Fenton, MO 63026)	

**SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF
PHARMACY AND DIERBERGS MARKETS, INC.
dba DIERBERGS FENTON CROSSING PHARMACY**

Come Now Dierbergs Markets, Inc. d/b/a Dierbergs Fenton Crossing Pharmacy (permit number 2000158538) (“Respondent” or the “Pharmacy”) ¹ and the Missouri Board of Pharmacy (“Board” or “Petitioner”) and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent’s Fenton Crossing Pharmacy, (permit number 2000158538) to operate a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against

¹ The Pharmacy subject to this agreement, order, discipline and remedial action is the Dierbergs Fenton Crossing Pharmacy, Permit Number 2000158538, only.

it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 2000158538, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo

JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo², for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Dierbergs Markets, Inc. d/b/a Dierbergs Fenton Crossing Pharmacy ("Respondent" or "the Pharmacy") is permitted by the Board as a pharmacy, Permit No. 2000158538. The Pharmacy is located at 450 Old Smizer Mill Rd. Fenton, MO 63026.

² All statutory references are to the 2000 Revised Statutes of Missouri, (Cum. Supp. 2013), unless otherwise stated.

3. Mark Greaves ("Greaves") was employed as Pharmacist-In-Charge ("PIC") of the Pharmacy at all relevant times herein.

4. On or about December 2, 2015, the Board was notified by the supervisor of the Pharmacy of suspected losses of Oxycodone.³

5. The losses were discovered after a physical inventory of controlled substances was taken by the Pharmacy subsequent to the termination of a pharmacy technician who was terminated for stealing cash from the cash register.

6. On or around December 4, 2015, Greaves admitted to having diverted approximately 1400 pills from the Pharmacy as follows:

A. Greaves admitted that he diverted Fioricet⁴ tablets from the Pharmacy for headaches starting in April, 2014. He consumed two to three pills per day until Fall, 2014 when his consumption increased to six to eight pills per day. His consumption level of six to eight pills of Fioricet per day continued until October, 2015.

B. Greaves admitted that he diverted Oxycodone from the Pharmacy from approximately August, 2014 to July/August, 2015. He diverted one bottle of Oxycodone 10mg, one bottle of Oxycodone 20mg, and two bottles of Oxycodone 30mg for a total of 400 Oxycodone pills.

7. On or about December 9, 2015, Greaves admitted orally and in writing to diverting an additional two to three partial bottles of Oxycodone 20mg from the Pharmacy from Summer 2014 to Summer 2015 which represented approximately 100 to 120 additional pills.

³ Oxycodone is a Schedule II controlled substance. §195.017.8(2)(uu), RSMo.

⁴ Fioricet is a legend drug containing a combination of acetaminophen, butalbital, and caffeine and is used to treat tension headaches that are caused by muscle contractions.

8. On or around February 25, 2016, Greaves admitted to consuming up to 3 tablets of Fioricet per day while at work and 5 to 6 tablets per day while not at work. He further admitted to consuming up to 10mg of Oxycodone per day on average until July 2015.

9. Greaves claims to have adjusted inventory in the Pharmacy system to match the number of physical tablets on hand in the Pharmacy when he diverted medication and also when he realized a shortage existed in any other medication dispensed by the Pharmacy in an effort to avoid any investigation of the Pharmacy.

10. Greaves did not have valid written prescriptions for Fioricet or Oxycodone.

11. Greaves also admitted to leaving his key to the controlled substances cabinet on the counter while he was working or when he left the Pharmacy such that others could access the Pharmacy's controlled substances cabinet.

12. On or around June 17, 2016, Greaves pleaded guilty before the United States District Court for the Eastern District of Missouri in Case No. 4:16CR250 RWS to violating 21 U.S.C. § 843(a)(3).

13. The Pharmacy filed Reports of Loss or Theft of Controlled Substances with the Drug Enforcement Administration and the Bureau of Narcotics and Dangerous Drugs on January 29, 2016.

14. These reports showed the following losses from July 4, 2014, to December 4, 2015:

Drug	Amount Lost
Alprazolam ⁵ 0.25mg	318
Alprazolam 0.5mg	1183
Alprazolam 1mg	1788

⁵ Alprazolam is a Schedule IV controlled substances pursuant to § 195.017.8(2)(a), RSMo.

Alprazolam 2mg	703
Hydrocodone/APAP 5/325mg ⁶	608
Hydrocodone/APAP 7.5/325mg	575
Hydrocodone/APAP 10/325mg	2078
Hydrocodone/IBU 7.5/200mg	195
Oxycodone 5mg	33
Oxycodone 10mg	39
Oxycodone 15mg	340
Oxycodone 20mg	952
Oxycodone 30mg	481
Oxycodone/APAP 5/325mg	194
Oxycodone/APAP 7.5/325mg	397
Oxycodone /APAP 10/325mg	1501
Total dosage units	11,385

Violations of Law

15. Greaves and/or the Pharmacy failed to provide effective controls and procedures to guard against the theft of controlled substances in violation of 19 CSR § 30-1.031(1)-(2), to wit:

- (1) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Department of Health shall use the security requirements set forth in 19 CSR 30-1.032-19 CSR 30-1.034 as standards for the physical security controls and operating procedures necessary to prevent diversion
- (2) Physical security controls shall be commensurate with the schedules and quantity of controlled substances in the possession of the registrant in normal business operations. If a controlled substance is transferred

⁶ Hydrocodone was rescheduled from a Schedule III to a Schedule II controlled substance on October 6, 2014. 21 §§ C.F.R. 1308.12, .13.

to a different schedule, or a noncontrolled substance is listed on any schedule, or the quantity of controlled substances in the possession of the registrant in normal business operations significantly increases, physical security controls shall be expanded and extended accordingly.

16. Missouri regulations also provide:

(H) Pharmacies must maintain adequate security in order to deter theft of drugs by personnel or the public. Sufficient alarm systems or locking mechanisms must be in place if the pharmacy is located in a facility into which the public has access and the pharmacy's hours of operation are different from those of the remainder of the facility.

20 CSR § 2220- 2.010(1)(H).

17. The Pharmacy failed to provide effective security for controlled substances in violation of Missouri law, to wit::

(1) Physical Security.

(A) Controlled substances listed in Schedules I and II shall be stored in a securely locked, substantially constructed cabinet.

(B) Controlled substances listed in Schedules III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse these substances throughout the stock of noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

19 CSR § 30-1.034(1)(A)-(B).

18. Federal law also provides guidance on effective security, to wit:

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion

(b) . . . In evaluating the overall security system of a registrant or applicant, the Administrator may consider any of the following facts as he may deem relevant to the need for strict compliance with security requirements:

* * *

(11) The adequacy of supervision over employees having access to manufacturing and storage areas;

* * *

(14) the adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; . . .

21 CFR § 1301.71(a)-(b).

19. The Pharmacy failed to provide effective controls and procedures to guard against theft and diversion of controlled substances leading to the loss of over 11,000 units of controlled substances from the Pharmacy.

20. Greave's and/or the Pharmacy's conduct as described herein caused the Pharmacy to be in violation of Section 338.100, RSMo, which states in relevant part:

1. Every permit holder of a licensed pharmacy shall cause to be kept in a uniform fashion consistent with this section a suitable file in which shall be preserved, for a period of not less than five years, the original or order of each drug which has been compounded or dispensed at such pharmacy, according to and in compliance with standards provided by the board, . . . The pharmacist in charge shall be responsible for complying with the permit holder's record-keeping system in compliance with this section. . . .

21. Greave's and/or the Pharmacy's conduct as described herein caused the Pharmacy to be in violation of 21 U.S.C. § 827 which states in relevant part:

(a) Inventory

Except as provided in subsection (c) of this section —

* * *

(3) on and after May 1, 1971, every registrant under this subchapter manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except

that this paragraph shall not require the maintenance of a perpetual inventory.

22. Greave's and/or the Pharmacy's conduct as described herein caused the Pharmacy to be in violation of Federal regulation 21 C.F.R. § 1304.21(a) which states in relevant part:

(a) Every registrant required to keep records pursuant to Sec. 1304.03 shall maintain on a current basis a complete and accurate record of each such substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.

23. By failing to provide effective controls and procedures to guard against theft and diversion of controlled substances, and by losing over 11,000 units of controlled substances from the Pharmacy, the Pharmacy is in violation of 19 CSR § 30-1.031(1)-(2), 20 CSR § 2220-2.010(1)(H), 19 CSR § 30-1.034(1)(A)-(B), 21 CFR 1301.71(a)-(b), §338.100, RSMo, 21 U.S.C. § 827, and 21 C.F.R. § 1304.21(a).

JOINT CONCLUSIONS OF LAW

24. The Pharmacy knew or should have known that it lost over 11,000 units of controlled substances over the course of at least a year and a half prior to the diversion being discovered by the Board.

25. Missouri law provides:

(O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.
20 CSR § 2220-2.010(1)(O).

26. Cause exists to discipline Respondent's permit to operate a pharmacy under §338.210.5, RSMo, which provides:

5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-in-charge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation. §338.210.5, RSMo.

27. Respondent's conduct is also cause for disciplinary action against its pharmacy permit under §338.055 RSMo, which provides:

2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

* * *

(5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;

* * *

(6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;

* * *

(13) Violation of any professional trust or confidence;

* * *

(15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government.

JOINT AGREED DISCIPLINARY ORDER

A. Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the

authority of §621.045.4(3), RSMo. Respondent's pharmacy permit, number 2000158538 shall be placed on **PROBATION for a period of THREE (3) YEARS** ("disciplinary period"). The terms of discipline shall be:

The following terms apply for the entire disciplinary period.

1. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.
2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.
3. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by the Respondent, and the individuals' current home addresses and telephone numbers.
4. If, after disciplinary sanctions have been imposed, the Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.
5. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.
6. Respondent shall not serve as an intern training facility for interns.
7. Respondent shall perform audits/reconciliations on all controlled substances throughout the period of probation. Within fifteen (15) days of the beginning

of probation, the Respondent shall conduct a physical inventory of said drugs. The physical inventory must be an exact count with no estimation. The Respondent shall then on a six (6) month cycle conduct a physical inventory and audit/reconciliation of said drugs for the previous six (6) month period. The Respondent shall report the results of each audit/reconciliation to the Board office within thirty (30) days of the audit/reconciliation date.

8. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

9. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

10. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

B. Upon the expiration of said discipline, Respondent's license as a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.

C. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

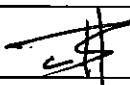
D. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

E. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

F. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. §1983, which

may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

<u> </u>	REQUESTS
	DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S PERMIT TO OPERATE AS A PHARMACY.

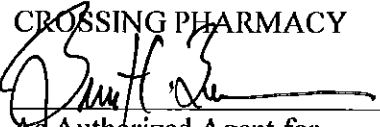
If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect 15 days after the document is signed by the Board's Executive Director.

RESPONDENT

DIERBERGS MARKETS, INC.
d/b/a DIERBERGS FENTON
CROSSING PHARMACY

By:


As Authorized Agent for
DIERBERGS MARKETS, INC.
d/b/a DIERBERGS FENTON
CROSSING PHARMACY

Printed: BRENT C. BEUMER
CORPORATE COUNSEL

Date: FEBRUARY 21, 2017

PETITIONER

MISSOURI BOARD OF
PHARMACY

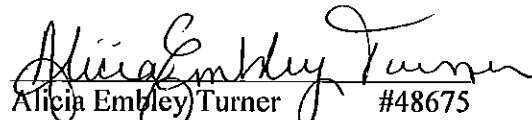
By:


KIMBERLY GRINSTON
Executive Director

Date: 3/2/17

NEWMAN, COMLEY & RUTH P.C.

By:


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